2021, will receive a notification about an opportunity to participate in the public comment session of the meeting. If you wish to speak during the public comment session, follow the instructions in the notification and identify which topic(s) you wish to address. We will do our best to accommodate requests to make public comments. Individuals and organizations with common interests are urged to consolidate or coordinate their comments and request time jointly. All requests to make a public comment during the meeting must be received by March 7, 2021, 11:59 p.m. Eastern Time. We will determine the amount of time allotted to each commenter, the approximate time each comment is to begin, and will select and notify participants by March 21, 2021. No commercial or promotional material will be permitted to be presented at the public meeting.

Streaming Webcast of the Public Meeting: This public meeting will also be held via Adobe Connect webcast: *https://collaboration.fda.gov/pdufavify21/.*

Transcripts: Please be advised that as soon as a transcript of the public meeting is available, it will be accessible at *https://www.regulations.gov.* It may be viewed at the Dockets Management Staff (see **ADDRESSES**). A link to the transcript will also be available on the internet at *https://www.fda.gov/forindustry/userfees/prescriptiondruguserfee/ucm446608.htm.*

Dated: January 11, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–00831 Filed 1–14–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

RIN 0991–ZA52

Making Permanent Regulatory Flexibilities Provided During the COVID–19 Public Health Emergency by Exempting Certain Medical Devices From Premarket Notification Requirements; Request for Information, Research, Analysis, and Public Comment on Opportunities for Further Science and Evidence-Based Reform of Section 510(k) Program

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Notice; request for information.

SUMMARY: To provide Americans with expanded access to certain medical devices to respond to the COVID–19 Public Health Emergency, FDA issued guidance documents providing numerous regulatory flexibilities, including a temporary waiver of premarket notification requirements under section 510(k) of the Food, Drug, and Cosmetic Act. For seven class I devices for which 510(k) premarket review as temporarily waived during the PHE, the Department of Health and Human Services is permanently exempting those seven (7) class I devices from the 510(k) requirement and is also proposing to exempt an additional 83 class II devices and 1 unclassified device class from the 510(k) requirement, for which premarket review had also been waived during the PHE. The Department is soliciting the public's views on whether premarket review should be permanently waived for some or all of these 83 devices and views on ways to improve the 510(k) premarket notification program.

DATES: Part III.A of this Notice shall be effective immediately on publication in the **Federal Register**. To be considered, responses and comments related to Part III.B of this Notice must be received electronically, within sixty days of publication in the **Federal Register** as provided below. The Department will consider information submitted by the public in response to Part IV of this Notice on a rolling basis, and until further notice.

ADDRESSES: You may submit comments through the Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name and docket number or Regulatory Information Number (RIN) for this rulemaking. All comments received will be posted to *http://regulations.gov,* including any personal information provided. For access to the docket to read background documents or comments received, go to *http://www.regulations.gov.* Comments must be identified by 0991–ZA52. Because of staff and resource limitations, all comments must be submitted electronically to *www.regulations.gov.* Follow the ''Submit a comment'' instructions.

Warning: Do not include any personally identifiable information (such as name, address, or other contact information) or confidential business information that you do not want publicly disclosed. All comments may be posted on the internet and can be retrieved by most internet search engines. No deletions, modifications, or redactions will be made to comments received.

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including personally identifiable or confidential business information that is included in a comment. You may wish to consider limiting the amount of personal information that you provide in any voluntary public comment submission you make. HHS may withhold information provided in comments from public viewing that it determines may impact the privacy of an individual or is offensive. For additional information, please read the Privacy Act notice that is available via the link in the footer of *http://www.regulations.gov.* Follow the search instructions on that website to view the public comments.

FOR FURTHER INFORMATION CONTACT: Dan Barry, 200 Independence Ave. SW, Washington, DC 20201; or by email at *daniel.barry@hhs.gov;* or by telephone at 1–877–696–6775.

SUPPLEMENTARY INFORMATION: The Administration is committed to creating a data-based regulatory process that appropriately balances benefits and costs. Consistent with the President's executive order on COVID–19 regulatory flexibilities, and Congress' direction in the 21st Century Cures Act, the Department is issuing this Notice to permanently exempt or proposing to permanently exempt certain class I and class II medical devices from the premarket notification requirement in section 510(k) of the Food, Drug, and Cosmetic Act, 21 U.S.C. 360(k). Under this notice, the Department is immediately making permanent the exemption of 7 class I device classes from the section 510(k) requirement and proposes to exempt an additional 84 class II and unclassified device classes from the same requirement on a permanent basis. These 91 devices were all subject a 510(k) waiving during the PHE.

I. Background

A. Statutory Framework

Under the Food, Drug, and Cosmetic Act (FD&C Act), medical devices are placed ''in three categories based on the risk that they pose to the public.'' [1] Class I devices, products ''that present no unreasonable risk of illness or injury,'' [2] are subject to general controls. FD&C Act 513(a)(1)(A), 21 U.S.C.

[1] *Medtronic, Inc.* v. *Lohr,* 518 U.S. 470, 476 (1996).

[2] *Id.* at 476–77.

360c(a)(1)(A). Class II devices are ''potentially more harmful'' than class I devices, and ''must comply with federal performance regulations known as 'special controls.''' [3] Class III devices carry the highest risk, in that they are for ''use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, or present[ ] a potential unreasonable risk of illness or injury.'' FD&C Act 513(a)(1)(C)(ii)(I)–(II), 21 U.S.C. 360c(a)(1)(C)(ii)(I)–(II).

Medical devices are generally subject to FDA premarket review in one of two forms. The first is premarket approval (PMA) review under section 515 of the FD&C Act, 21 U.S.C. 360e. This form of ''rigorous'' review, analogous to FDA review of a New Drug Application for a ''new drug,'' requires manufacturers to ''submit detailed information regarding the safety and efficacy of their devices, which the FDA then reviews.'' [4] During the mid-1990s, FDA reported spending ''an average of 1,200 hours on each [PMA] submission,'' [5] though the time for review has likely increased since *Lohr* was decided.

The second form of premarket review is the premarket notification process, which is commonly referred to as the 510(k) process after section 510(k) of the FD&C Act, 21 U.S.C. 360(k). Generally, under the 510(k) process, a device that is ''substantially equivalent'' to another legally marketed predicate device is ''cleared'' (as opposed to ''approved'') [6] by FDA for legal marketing in the United States. *See* FD&C Act 510(k), 513(i), 21 U.S.C. 360(k), 360c(i). FDA regulations specify the required contents of 510(k) notifications, including labeling, intended use, and clinical and performance data requirements. 21 CFR 807.92. FDA previously reported requiring ''an average of only 20 hours'' to complete a 510(k) review,[7] which would be around 60 times less than the time required for PMA review.

Obtaining either a PMA approval or a 510(k) clearance to legally market a medical device is expensive and time-consuming. According to a 2010 survey of medical device companies, ''the average total cost from concept to approval [of a PMA device] was approximately $94 million, with $75 million spent on stages linked to the FDA.'' [8] For PMAs, survey respondents reported ''that it actually took them an average of 54 months to work with the FDA from first communication to approval.'' [9]

While 510(k) devices trod a swifter, less expensive path to market than PMA devices do, the same survey found that ''the average total cost for participants to bring a low-to-moderate-risk 510(k) product from concept to clearance was approximately $31 million, with $24 million spent on FDA dependent and/or related activities.'' [10] Respondents also reported ''an average of 10 months from first filing to clearance'' for a 510(k) device.[11] The survey authors acknowledged that respondents ''were most likely those companies working on innovative, new medical technologies that required clinical data to get through the FDA rather those seeking relatively simple extensions to low-risk, ubiquitous product lines already in existence.'' [12] Nevertheless, the survey found the average total cost connected to the ''Process of Obtaining [a] 510(k) [clearance]'' to be more than $4 million per product.[13] Even if these estimates overstate costs by a factor of ten, a firm could still spend $2.4 million ''on FDA dependent and/or related activities,'' to include an estimated $400,000 on the 510(k) clearance process itself. Similarly, even if the survey respondents overstated delays, and the actual time were much closer to FDA's goal date of 90 days for review, it is undisputed that the 510(k) clearance process delays a device's introduction to the market.

A 2014 report on antibacterial products produced for the Assistant Secretary for Planning and Evaluation (ASPE) contains similar findings. The report noted that, to conduct a pivotal clinical study to support a 510(k) submission for a MRSA point-of-care diagnostic, a manufacturer could expect to spend ''from a low of $250,000 to as high as $4.0 million.'' [14] The report estimated the cost to prepare and submit a 510(k) application ''at $100,000'' while acknowledging the amount ''could be highly variable depending on device characteristics.'' [15]

These costs are barriers to new market entrants. To the extent imposing the section 510(k) premarket notification on a device does not create corresponding safety and efficacy benefits for Americans, those barriers are unjustified. Such barriers warrant scrutiny, particularly when market incumbents have an interest in retaining them. As FDA acknowledged in a 1975 proposed rule in the analogous context of drug approvals, ''the manufacturer who holds the 'pioneer' NDA for a drug may well have an economic interest in retaining the new drug status of that drug'' because ''[a]s long as either a full or an abbreviated NDA is required, entry into the market place, and thus increased competition is impeded.'' [16] FDA noted its belief ''that it was not the intention of Congress that section 505 of the [FD&C Act] would be used as an economic trade barrier.'' [17]

[3] *Lohr,* 518 U.S. at 477; *see also* FD&C Act 513(a)(1)(B), 21 U.S.C. 360c(a)(1)(B).

[4] *Lohr,* 518 U.S. at 477.

[5] *Id.*

[6] *See* 21 CFR 807.97 (providing that ''determination by the Commissioner that the device intended for introduction into commercial distribution is substantially equivalent'' to a predicate device ''does not in any way denote official approval of the device'').

[7] *Id.*

[8] Josh Makower, Aabed Meer & Lyn Denend, *FDA Impact on U.S. Medical Technology Innovation: A Survey of Over 200 Medical Device Companies,* at 7 (Nov. 2010), *https://www.medtecheurope.org/wp-content/uploads/2015/07/01112010_FDA-impact-on-US-medical-technology-innovation_Backgrounder.pdf.* During a 2011 hearing before a House subcommittee, the Director for the Center for Devices and Radiological Health (CDRH) raised concerns regarding the methodology used in this study. *FDA Medical Device Approval: Is There a Better Way?, Hearing Before the H. Subcomm. on Health Care, District of Columbia, Census and the National Archives,* 112th Cong. 29 (2011) (hereinafter the ''2011 Hearing''). The CDRH Director's criticisms largely focused on the report's comparison of FDA's regulation of medical devices to the European Union's regulatory system. The CDRH Director otherwise acknowledged that FDA does not ''do cost analyses for what the manufacturers are doing'' and that the agency ''would not know of the total cost to a particular company.'' *Id.* at 32. Here, the Department is citing this study for 510(k) cost and time estimates, not for purposes of comparing the U.S. and E.U. medical device regulatory systems.

[9] *Id.* at 22.

[10] *Id.* at 7.

[11] *Id.* at 22.

[12] *Id.* at 29, fig. 10.

[13] *Id.*

[14] Aylin Sertkaya et al., *Analytical Framework for Examining the Value of Antibacterial Products,* at 5–3 (Apr. 15, 2014).

[15] *Id.* at 5–4.

[16] 40 FR 26142, 26148 (June 20, 1975).

[17] *Id.*

Congress has taken action to ensure that the section 510(k) premarket notification process does not create undue economic barriers for new medical devices. Under the FD&C Act, the Secretary is authorized to exempt class I and II medical devices from the 510(k) requirement if the Secretary finds those devices ''no longer require[ ] a report under section [510](k) to provide reasonable assurance of safety and effectiveness.'' FD&C Act 510(*l*)(2), 510(m)(1)(A)(i), 21 U.S.C. 360(*l*)(2), 360(m)(1)(A)(i). Congress did this in part to ''allow the Secretary to expend limited premarket review resources on potentially risky and technologically advanced devices'' so that ''the public continues to be adequately protected and will still benefit from the earlier availability of new products.'' [18] In section 3054 of the 21st Century Cures Act, Public Law 114–255, 130 Stat. 1033, 1126–27 (Dec. 13, 2016), Congress imposed additional requirements on the Secretary to take action to affirmatively review class I and II devices to determine whether they are exempt from the 510(k) requirement. This Notice is responsive to these previous mandates.

B. Waiver of Premarket Notification Requirement During COVID–19 PHE

Beginning in March 2020, in response to the COVID–19 Public Health Emergency (PHE), FDA issued a series of guidance documents designed to provide the private sector with regulatory flexibility to meet the sudden, increased need for personal protective equipment, disinfectant products, and other devices to combat the pandemic. The table below presents the various guidance documents issued in April 2020 to assist in the response to the PHE.

TABLE 1—LIST OF FDA MEDICAL DEVICE ENFORCEMENT POLICIES RESPONSIVE TO PHE

Title of guidance	Date
Enforcement Policy for Clinical Electronic Thermometers During the Coronavirus Disease 2019 (COVID–19) Public Health Emergency.	April 2020.
Enforcement Policy for Imaging Systems During the Coronavirus Disease 2019 (COVID–19) Public Health Emergency.	April 2020.
Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID–19) Public Health Emergency (Revised).	May 2020.
Enforcement Policy for Gowns, Other Apparel, and Gloves During the Coronavirus Disease (COVID–19) Public Health Emergency.	March 2020.
Enforcement Policy for Sterilizers, Disinfectant Devices, and Air Purifiers During the Coronavirus Disease 2019 (COVID–19) Public Health Emergency.	March 2020.
Enforcement Policy for Digital Health Devices For Treating Psychiatric Disorders During the Coronavirus Disease 2019 (COVID–19) Public Health Emergency.	April 2020.
Enforcement Policy for Extracorporeal Membrane Oxygenation and Cardiopulmonary Bypass Devices During the Coronavirus Disease 2019 (COVID–19) Public Health Emergency.	April 2020.
Enforcement Policy for Infusion Pumps and Accessories During the Coronavirus Disease 2019 (COVID–19) Public Health Emergency.	April 2020.
Enforcement Policy for Non-Invasive Fetal and Maternal Monitoring Devices Used to Support Patient Monitoring During the Coronavirus Disease 2019 (COVID–19) Public Health Emergency.	April 2020.
Enforcement Policy for Non-Invasive Remote Monitoring Devices Used to Support Patient Monitoring During the Coronavirus Disease-2019 (COVID–19) Public Health Emergency (Revised).	March 2020 (original). June 2020 (revised). October 2020 (revised).
Enforcement Policy for Remote Digital Pathology Devices During the Coronavirus Disease 2019 (COVID–19) Public Health Emergency.	April 2020.
Enforcement Policy for Remote Ophthalmic Assessment and Monitoring Devices During the Coronavirus Disease 2019 (COVID–19) Public Health Emergency.	April 2020.
Enforcement Policy for Ventilators and Accessories and Other Respiratory Devices During the Coronavirus Disease 2019 (COVID–19) Public Health Emergency.	March 2020.

As FDA explained in its clinical thermometer guidance, FDA provided these flexibilities to ''ensure the availability of equipment that might offer some benefit to health care providers and the general public during the public health emergency.'' [19] To that end, among other things, FDA announced that the agency ''does not intend to object to the distribution and use of clinical thermometers that are not currently 510(k) cleared.'' [20] Some of the flexibilities, such as those extended to remote patient monitoring, have helped facilitate telemedicine during the PHE. FDA extended similar flexibility to additional devices in other guidance documents shown in Table 1.

II. HHS' Review of 510(k) Premarket Notification Flexibilities

On May 19, 2020, the President issued Executive Order No. 13924, instructing ''[t]he heads of all agencies'' to ''review any regulatory standards that they have temporarily rescinded, suspended, modified, or waived during the public health emergency,'' in order to ''determine which, if any, would promote economic recovery if made permanent.'' [21] Further, Congress already instructed the Secretary to consider whether to exempt class I and II devices from the section 510(k) requirement ''at least once every 5 years.'' FDCA 510(*l*)(2), 510(m)(1)(A), 21 U.S.C. 360(*l*)(2), 360(m)(1)(A).

Consistent with the President's executive order, and Congress' direction in the 21st Century Cures Act, the Department conducted a data-driven review to determine whether temporary waiver of the section 510(k) premarket notification requirement for some devices during the PHE should be made permanent. The flexibilities given by FDA during the PHE presented the Department with a unique opportunity to analyze the adverse event records of

[18] H.R. Conf. Rep. 105–399, at 96 (1997).

[19] FDA, Enforcement Policy for Clinical Electronic Thermometers During the Coronavirus Disease 2019 (COVID–19) Public Health Emergency, at 3 (Apr. 2020), *https://www.fda.gov/media/136698/download.*

[20] *Id.*

[21] 85 FR 31353, 31356 (May 22, 2020).

devices in periods of time with and without the premarket notification requirement. In view of this, the overarching question for HHS was whether premarket notification provided corresponding safety and efficacy benefits. Below the Department describes the methodology for its review and the results of the same.

A. Methodology

HHS first reviewed the thirteen FDA guidance documents listed in Table 1 to determine which device types are subject to those enforcement policies. The Department identified 221 unique device types. HHS analyzed those device types using FDA's Product Code Database [22] to determine how many of those devices require premarket review. Of those 221 device types, the Department determined that 5 require a PMA, 29 are exempt from the 510(k) requirement, 3 are marketed subject to FDA's enforcement discretion, and 184 require 510(k) clearance prior to marketing. Of the 184 devices types that would require 510(k) clearance without the guidance documents list in Table 1, 10 are class I devices, 173 are class II devices, and 1 is unclassified. These 184 devices are referred to collectively in this Notice as the ''Review Devices.''

FDA maintains a publicly available adverse event reporting database called the Manufacturer and User Facility Device Experience database or MAUDE. MAUDE ''houses [medical device reports or] MDRs submitted to the FDA by mandatory reports (manufacturers, importers and device user facilities) and voluntary reporters such as health care professionals, patients and consumers.'' [23] Like any ''passive surveillance system,'' MAUDE has ''limitations, including the potential submission of incomplete, inaccurate, untimely, or biased data,'' which means ''incidence or prevalence of an event cannot be determined from this reporting system alone due to under-reporting of events, inaccuracies in reports, lack of verification that the device caused the reported event, and lack of information about frequency of device use.'' [24] Even with the system's limitations, MAUDE is an important source of data. FDA has previously used data from MAUDE to inform the agency's decision making.[25] Products liability plaintiffs also make use of the database.[26] As the CDRH Director previously explained to Congress, systems like MAUDE set the United States apart from jurisdictions like the European Union that ''do not have publicly available centralized data base[s] for that kind of information.'' [27]

In this review, the Department performed searches of the Review Devices in FDA's online searchable MAUDE database. Updated on a monthly basis, the online ''searchable database data contains the last 10 year's data'' of reports ''on medical devices which may have malfunctioned or caused a death or serious injury.'' [28] HHS entered the three-letter product code for each Review Device into the online MAUDE database. HHS then collected data on the number of reports for each Review Device from November 1, 2010 to November 30, 2020, tabulating the reports from November 1, 2010 to the beginning of the PHE, and for the time period subsequent the beginning of the PHE to November 30, 2020.

B. Results

Of the 184 Review Devices, HHS found there were 120 or more MAUDE reports for 74 devices and less than 100 MAUDE reports for the 110 other devices during the last ten years. This means roughly 60% of the Review Devices have less than 100 MAUDE reports over the last ten years. Of those 110 devices, 35 devices had no MAUDE reports from November 1, 2010 to November 30, 2020. Those 35 devices are shown in Table 2 below.

TABLE 2—REVIEW DEVICES WITH ZERO ADVERSE EVENT REPORTS IN MAUDE FOR THE TIME PERIOD NOVEMBER 1, 2010 TO NOVEMBER 30, 2020

Device description	Device class	Product code	Section in 21 CFR
Powder-Free Polychloroprene Patient Examination Glove	I	OPC	880.6250
Ventilator, Continuous, Minimal Ventilatory Support, Home Use	II	NQY	868.5895
Airway Monitoring System	II	OQU	868.5730
Impedance Measuring Device Utilizing Oscillation Techniques	II	PNV	868.1840
Gauge, Pressure, Coronary, Cardiopulmonary Bypass	II	DXS	870.4310
Valve, Pressure Relief, Cardiopulmonary Bypass	II	MNJ	870.4400
Oximeter, Tissue Saturation, Reprocessed	II	NMD	870.2700
Multivariate Vital Signs Index	II	PLB	870.2300
Electrocardiograph Software For Over-The-Counter Use	II	QDA	870.2345
Sterilizer, Dry Heat	II	KMH	880.6870
Check Valve, Retrograde Flow (In-Line)	II	MJF	880.5440
Intravascular Administration Set, Automated Air Removal System	II	OKL	880.5445
Neuraxial Administration Set—Intrathecal Delivery	II	PYR	880.5440
High Level Disinfection Reprocessing Instrument For Ultrasonic Transducers, Liquid	II	PSW	892.1570
Pediatric/Child Facemask	II	OXZ	878.4040
Normalizing Quantitative Electroencephalograph Software	II	OLU	882.1400
Computerized Cognitive Assessment Aid	II	PKQ	882.1470
Physiological Signal Based Seizure Monitoring System	II	POS	882.1580
Computerized Behavioral Therapy Device For Psychiatric Disorders	II	PWE	882.5801
Monitor, Phonocardiographic, Fetal	II	HFP	884.2640
Monitor, Cardiac, Fetal	II	KXN	884.2600
Digital Pathology Display	II	PZZ	864.3700
Digital Pathology Image Viewing And Management Software	II	QKQ	864.3700

[22] FDA, *Product Classification Database, https://www.fda.gov/medical-devices/classify-your-medical-device/product-code-classification-database.*

[23] FDA, *MAUDE—Manufacturer and User Facility Device Experience, https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm.*

[24] *Id.*

[25] *E.g.,* 85 FR 70003, 70006 (Dec. 20, 2019).

[26] *See* Patrick J. McGrather, *The FDA's MAUDE: Useful Insights for Medical Devices* (Oct. 31, 2017), *https://www.americanbar.org/groups/litigation/committees/mass-torts/practice/2017/manufacture-and-user-facility-device-experience/.*

[27] 2011 Hearing at 30.

[28] FDA, *Manufacturer and User Facility Device Experience Database—(MAUDE), https://www.fda.gov/medical-devices/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities/manufacturer-and-user-facility-device-experience-database-maude.*

TABLE 2—REVIEW DEVICES WITH ZERO ADVERSE EVENT REPORTS IN MAUDE FOR THE TIME PERIOD NOVEMBER 1, 2010 TO NOVEMBER 30, 2020—Continued

Device description	Device class	Product code	Section in 21 CFR
System, Imaging, Holography, Acoustic	II	NCS	892.1550
Lung Computed Tomography System, Computer-Aided Detection	II	OEB	892.2050
Chest X-Ray Computer Aided Detection	II	OMJ	892.2050
Computer-Assisted Diagnostic Software For Lesions Suspicious For Cancer	II	POK	892.2060
Radiological Computer-Assisted Triage And Notification Software	II	QAS	892.2080
Radiological Computer Assisted Detection/Diagnosis Software For Fracture	II	QBS	892.2090
Radiological Computer Assisted Detection/Diagnosis Software For Lesions Suspicious For Cancer.	II	QDQ	892.2090
Radiological Computer-Assisted Prioritization Software For Lesions	II	QFM	892.2080
X-Ray Angiographic Imaging Based Coronary Vascular Simulation Software Device	II	QHA	892.1600
Automated Radiological Image Processing Software	II	QIH	892.2050
Image Acquisition And/Or Optimization Guided By Artificial Intelligence	II	QJU	892.2100
Apparatus, Vestibular Analysis	Unclassified	LXV	N/A

Another 43 devices had no reports in MAUDE following declaration of the PHE, and the waiver of the 510(k) premarket notification requirement, with anywhere from 1 to 86 reports in MAUDE prior to the PHE for those same devices. For the ten-year period spanning November 1, 2010 to November 30, 2020, there were a total of 637 reports in MAUDE associated with theses 43 devices listed in Table 3.1. This equates to about 1.5 MAUDE reports per year per device. Table 3.1 below shows each device with the corresponding number of adverse events before and after the PHE.

TABLE 3.1—REVIEW DEVICES WITH ZERO ADVERSE EVENTS POST-PHE AND 86 OR FEWER ADVERSE EVENTS PRE-PHE IN MAUDE

Device description	Device class	Product code	Section in 21 CFR	MAUDE events November 1, 2010 to PHE	MAUDE events Post-PHE to November 30, 2020
Patient Examination Glove, Specialty	I	LZC	880.6250	46	0
Radiation Attenuating Medical Glove	I	OPH	880.6250	1	0
Powder-Free Non-Natural Rubber Latex Surgeon's Gloves	I	OPA	878.4460	1	0
Powder-Free Guayle Rubber Examination Glove	I	OIG	880.6250	2	0
Latex Patient Examination Glove	I	LYY	880.6250	48	0
Meter, Peak Flow, Spirometry	II	BZH	868.1860	27	0
Monitor, Apnea, Facility Use	II	FLS	868.2377	86	0
Monitor, Apnea, Home Use	II	NPF	868.2377	41	0
Oximeter, Reprocessed	II	NLF	870.2700	65	0
Stethoscope, Electronic	II	DQD	870.1875	2	0
Defoamer, Cardiopulmonary Bypass	II	DTP	870.4230	4	0
Filter, Blood, Cardiotomy Suction Line, Cardiopulmonary Bypass	II	JOD	870.4270	2	0
Detector, Bubble, Cardiopulmonary Bypass	II	KRL	870.4205	44	0
Cpb Check Valve, Retrograde Flow, In-Line	II	MJJ	870.4400	12	0
Sterilizer, Ethylene-Oxide Gas	II	FLF	880.6860	29	0
Cabinet, Ethylene-Oxide Gas Aerator	II	FLI	880.6100	2	0
Purifier, Air, Ultraviolet, Medical	II	FRA	880.6500	1	0
Cleaner, Air, Medical Recirculating	II	FRF	880.5045	7	0
Controller, Infusion, Intravascular, Electronic	II	LDR	880.5725	27	0
Cleaners, Medical Devices	II	MDZ	880.6992	5	0
Percutaneous, Implanted, Long-Term Intravascular Catheter Accessory For Catheter Position.	II	OMF	880.5970	9	0
N95 Respirator With Antimicrobial/Antiviral Agent For Use By The General Public In Public Health Medical Emergencies.	II	ORW	880.6260	1	0
Two Or More Sterilant Sterilizer	II	PJJ	880.6860	6	0
High Level Disinfection Reprocessing Instrument For Ultrasonic Transducers, Mist.	II	OUJ	892.1570	3	0
Gown, Patient	II	FYB	878.4040	1	0
Surgical Mask With Antimicrobial/Antiviral Agent	II	OUK	878.4040	1	0
Cerebral Oximeter	II	QEM	870.2700	2	0
Device, Sleep Assessment	II	LEL	882.5050	4	0
Standard Polysomnograph With Electroencephalograph	II	OLV	882.1400	9	0
Source Localization Software For Electroencephalograph Or Magnetoencephalograph.	II	OLX	882.1400	2	0
Automatic Event Detection Software For Polysomnograph With Electroencephalograph.	II	OLZ	882.1400	1	0
Amplitude-Integrated Electroencephalograph	II	OMA	882.1400	1	0

TABLE 3.1—REVIEW DEVICES WITH ZERO ADVERSE EVENTS POST-PHE AND 86 OR FEWER ADVERSE EVENTS PRE-PHE IN MAUDE—Continued

Device description	Device class	Product code	Section in 21 CFR	MAUDE events November 1, 2010 to PHE	MAUDE events Post-PHE to November 30, 2020
Automatic Event Detection Software For Full-Montage Electroencephalograph.	II	OMB	882.1400	4	0
Burst Suppression Detection Software For Electroencephalograph	II	ORT	882.1400	1	0
Monitor, Heart Rate, Fetal, Ultrasonic	II	HEL	884.2660	12	0
Transducer, Ultrasonic, Obstetric	II	HGL	884.2960	6	0
Uterine Electromyographic Monitor	II	OSP	884.2720	3	0
Tonometer, Ac-Powered	II	HKX	886.1930	1	0
Tonometer, Manual	II	HKY	886.1930	8	0
Automated Digital Image Manual Interpretation Microscope	II	OEO	864.1860	1	0
System, X-Ray, Tomographic	II	IZF	892.1740	35	0
Analyzer, Medical Image	II	MYN	892.2070	1	0
C-Arm Fluoroscopic X-Ray System	II	RCC	892.1650	73	0

The Department further analyzed the details of the MAUDE reports listed in Table 3.1. For the 5 class I glove devices listed, there were 98 reports. As shown in Table 3.2 below, after review of the detailed narratives for those 98 reports, they can be broken down into eight categories.

TABLE 3.2—MAUDE REPORT BREAKDOWN FOR 5 CLASS I DEVICES IN TABLE 3.1

Device description (Product Code)	MAUDE report category							
	Rip/tear/ hole	Discolor/ debris	Allergy/skin issue	Not device related	Improper use	Mislabeled	Odor	Total
Patient Examination Glove, Specialty (LZC)	22	19	4	1	0	0	0	46
Radiation Attenuating Medical Glove (OPH)	0	0	0	0	1	0	0	1
Powder-Free Non-Natural Rubber Latex Surgeon's Gloves (OPA)	0	0	1	0	0	0	0	1
Powder-Free Guayle Rubber Examination Glove (OIG)	0	0	2	0	0	0	0	2
Latex Patient Examination Glove (LYY)	6	7	29	4	0	1	1	48
Total	28	26	36	5	1	1	1	98

More than half of the reports (55%) related to material flaws such as tears, discoloration, or foreign debris in the gloves. For the 36 allergic reaction reports, there was only one report connected with a hospital visit for which the patient was ultimately monitored and discharged. There are 5 MAUDE events from which the report narrative does not provide a basis to infer that the device itself caused the harm.[29] None of the 98 reports involved a death.

The 38 class II devices listed in Table 3.1 were connected to another 539 MAUDE reports. Of those reports, 322 (59.7%) involved device malfunctions, 71 (13.2%) involved injuries, 22 (4.1%) involved deaths, and 124 (23%) have the event type listed as ''other'' or ''NA.'' Table 3.3 below provides the breakdown of the 539 MAUDE reports by device type.

TABLE 3.3—MAUDE REPORT BREAKDOWN FOR 38 CLASS II DEVICES IN TABLE 3.1

Device description	Product code	MAUDE report category					
		Malfunction	Injury	Death	Other	NA	Total
Meter, Peak Flow, Spirometry	BZH	26	1	0	0	0	27
Monitor, Apnea, Facility Use	FLS	52	9	16	9	0	86
Monitor, Apnea, Home Use	NPF	34	5	2	0	0	41
Oximeter, Reprocessed	NLF	49	14	0	0	2	65
Stethoscope, Electronic	DQD	1	0	0	1	0	2
Defoamer, Cardiopulmonary Bypass	DTP	3	1	0	0	0	4
Filter, Blood, Cardiotomy Suction Line, Cardiopulmonary Bypass	JOD	1	0	0	1	0	2

[29] For example, there was one MAUDE incident where a user reported suffering a third-degree burn after ''pouring boiling nitric acid into a beaker and without warning a chemical reaction occurred causing acid to spill onto the wrist.'' Nothing in the report indicates the gloves themselves caused the burn or otherwise exacerbated the burn.

TABLE 3.3—MAUDE REPORT BREAKDOWN FOR 38 CLASS II DEVICES IN TABLE 3.1—Continued

Device description	Product code	MAUDE report category					
		Malfunction	Injury	Death	Other	NA	Total
Detector, Bubble, Cardiopulmonary Bypass	KRL	33	0	0	1	10	44
Cpb Check Valve, Retrograde Flow, In-Line	MJJ	11	1	0	0	0	12
Sterilizer, Ethylene-Oxide Gas	FLF	7	9	0	1	12	29
Cabinet, Ethylene-Oxide Gas Aerator	FLI	0	2	0	0	0	2
Purifier, Air, Ultraviolet, Medical	FRA	1	0	0	0	0	1
Cleaner, Air, Medical Recirculating	FRF	6	0	0	0	1	7
Controller, Infusion, Intravascular, Electronic	LDR	27	0	0	0	0	27
Cleaners, Medical Devices	MDZ	4	0	0	1	0	5
Percutaneous, Implanted, Long-Term Intravascular Catheter Accessory For Catheter Position.	OMF	3	2	0	4	0	9
N95 Respirator With Antimicrobial/Antiviral Agent For Use By The General Public In Public Health Medical Emergencies.	ORW	1	0	0	0	0	1
Two Or More Sterilant Sterilizer	PJJ	0	6	0	0	0	6
High Level Disinfection Reprocessing Instrument For Ultrasonic Transducers, Mist.	OUJ	1	1	0	1	0	3
Gown, Patient	FYB	0	0	1	0	0	1
Surgical Mask With Antimicrobial/Antiviral Agent	OUK	0	1	0	0	0	1
Cerebral Oximeter	QEM	1	1	0	0	0	2
Device, Sleep Assessment	LEL	4	0	0	0	0	4
Standard Polysomnograph With Electroencephalograph	OLV	7	2	0	0	0	9
Source Localization Software For Electroencephalograph Or Magnetoencephalograph.	OLX	1	1	0	0	0	2
Automatic Event Detection Software For Polysomnograph With Electroencephalograph.	OLZ	0	1	0	0	0	1
Amplitude-Integrated Electroencephalograph	OMA	1	0	0	0	0	1
Automatic Event Detection Software For Full-Montage Electroencephalograph.	OMB	1	0	0	1	2	4
Burst Suppression Detection Software For Electroencephalograph.	ORT	1	0	0	0	0	1
Monitor, Heart Rate, Fetal, Ultrasonic	HEL	9	2	1	0	0	12
Transducer, Ultrasonic, Obstetric	HGL	0	6	0	0	0	6
Uterine Electromyographic Monitor	OSP	1	1	1	0	0	3
Tonometer, Ac-Powered	HKX	0	0	0	0	1	1
Tonometer, Manual	HKY	3	4	0	1	0	8
Automated Digital Image Manual Interpretation Microscope	OEO	1	0	0	0	0	1
System, X-Ray, Tomographic	IZF	31	1	1	1	1	35
Analyzer, Medical Image	MYN	1	0	0	0	0	1
C-Arm Fluoroscopic X-Ray System	RCC	0	0	0	1	72	73
Total		322	71	22	23	101	539

An additional 32 devices had from 1 to 32 reports in MAUDE after the PHE began and anywhere from 1 to 78 reports in MAUDE from November 1, 2010 to the start of the PHE. These devices are shown in Table 4.1 below.

TABLE 4.1—REVIEW DEVICES WITH MAUDE REPORTS BEFORE AND AFTER PHE

Device description	Device class	Product code	Section in 21 CFR	MAUDE events November 1, 2010 to PHE	MAUDE events Post-PHE to November 30, 2020
Vinyl Patient Examination Glove	I	LYZ	880.6250	40	1
Mechanical Ventilator	II	ONZ	868.5895	2	1
Cannula, Arterial, Cardiopulmonary Bypass (Cpb), Embolism Protection.	II	NCP	870.4210	6	1
Dual Lumen Ecmo Cannula	II	PZS	870.4100	2	4
Respirator, N95, For Use By The General Public In Public Health Medical Emergencies.	II	NZJ	880.6260	1	1
Sterilizer Automated Loading System	II	PEC	880.6880	8	1
Infusion Safety Management Software	II	PHC	880.5725	6	1
Gown, Isolation, Surgical	II	FYC	878.4040	12	1
Non-Normalizing Quantitative Electroencephalograph Software	II	OLT	882.1400	12	1
Monitor, Ultrasonic, Fetal	II	KNG	884.2660	16	2
Whole Slide Imaging System	II	PSY	864.3700	2	1
Oxygenator, Long Term Support Greater Than 6 Hours	II	BZG	868.1840	10	1
Transmitters And Receivers, Electrocardiograph, Telephone	II	BZQ	868.2375	38	8

TABLE 4.1—REVIEW DEVICES WITH MAUDE REPORTS BEFORE AND AFTER PHE—Continued

Device description	Device class	Product code	Section in 21 CFR	MAUDE events November 1, 2010 to PHE	MAUDE events Post-PHE to November 30, 2020
Extracorporeal System For Long-Term Respiratory/Cardiopulmonary Failure.	II	NFB	868.5905	24	1
Catheter, Percutaneous, Intraspinal, Short Term	II	NHJ	868.5905	18	2
Implanted Subcutaneous Securement Catheter	II	NHK	868.5905	78	1
Subcutaneous Implanted Apheresis Port	II	QAV	868.5454	0	1
Non-Coring (Huber) Needle	II	BYS	870.4100	0	1
Administrations Sets With Neuraxial Connectors	II	DXH	870.2920	18	5
Port & Catheter, Implanted, Subcutaneous, Intraventricular	II	QJZ	870.4100	0	12
Hood, Surgical	II	MAJ	868.5120	17	1
N95 Respirator With Antimicrobial/Antiviral Agent	II	OKC	880.5970	16	1
Reduced- Montage Standard Electroencephalograph	II	PTD	880.5965	40	32
Monitor, Uterine Contraction, External (For Use In Clinic)	II	PTI	880.5570	36	10
Coil, Magnetic Resonance, Specialty	II	PWH	880.5440	0	5
Solid State Fluoroscopic X-Ray Imager	II	LKG	882.5550	20	1
Oxygenator, Long Term Support Greater Than 6 Hours	II	FXY	878.4040	20	1
Transmitters And Receivers, Electrocardiograph, Telephone	II	ONT	878.4040	0	1
Extracorporeal System For Long-Term Respiratory/Cardiopulmonary Failure.	II	OMC	882.1400	0	1
Catheter, Percutaneous, Intraspinal, Short Term	II	HFM	884.2720	13	1
Implanted Subcutaneous Securement Catheter	II	MOS	892.1000	72	1
Subcutaneous Implanted Apheresis Port	II	QHY	892.1650	0	1

Table 4.2 presents the devices in Table 4.1 broken down by type of MAUDE. Of the 630 MAUDE reports analyzed, the majority (383 or 60.7%) involved product malfunctions with a limited number connected to death (24 or 3.8%).

TABLE 4.2—REVIEW DEVICES IN TABLE 4.1 BY MAUDE REPORT

Device descriptions	Device class	Product code	MAUDE Reports					
			Malfunction	Death	Injury	Other	NA	Total
Vinyl Patient Examination Glove	I	LYZ	20	0	19	1	1	41
Mechanical Ventilator	II	ONZ	1	1	1	0	0	3
Cannula, Arterial, Cardiopulmonary Bypass (Cpb), Embolism Protection.	II	NCP	2	0	5	0	0	7
Dual Lumen Ecmo Cannula	II	PZS	1	1	4	0	0	6
Respirator, N95, For Use By The General Public In Public Health Medical Emergencies.	II	NZJ	1	0	1	0	0	2
Sterilizer Automated Loading System	II	PEC	7	0	2	0	0	9
Infusion Safety Management Software	II	PHC	7	0	0	0	0	7
Gown, Isolation, Surgical	II	FYC	12	0	1	0	0	13
Non-Normalizing Quantitative Electroencephalograph Software.	II	OLT	11	2	0	0	0	13
Monitor, Ultrasonic, Fetal	II	KNG	2	1	15	0	0	18
Whole Slide Imaging System	II	PSY	2	0	1	0	0	3
Oxygenator, Long Term Support Greater Than 6 Hours.	II	BZG	7	0	2	1	1	11
Transmitters And Receivers, Electrocardiograph, Telephone.	II	BZQ	38	5	3	0	0	46
Extracorporeal System For Long-Term Respiratory/ Cardiopulmonary Failure.	II	NFB	11	4	9	1	0	25
Catheter, Percutaneous, Intraspinal, Short Term	II	NHJ	10	1	9	0	0	20
Implanted Subcutaneous Securement Catheter	II	NHK	68	4	6	0	1	79
Subcutaneous Implanted Apheresis Port	II	QAV	1	0	0	0	0	1
Non-Coring (Huber) Needle	II	BYS	1	0	0	0	0	1
Administrations Sets With Neuraxial Connectors	II	DXH	9	1	9	0	4	23
Port & Catheter, Implanted, Subcutaneous, Intraventricular.	II	QJZ	9	1	2	0	0	12
Hood, Surgical	II	MAJ	12	0	6	0	0	18
N95 Respirator With Antimicrobial/Antiviral Agent	II	OKC	12	0	3	1	1	17
Reduced- Montage Standard Electroencephalograph.	II	PTD	52	1	19	0	0	72
Monitor, Uterine Contraction, External (For Use In Clinic).	II	PTI	22	0	24	0	0	46
Coil, Magnetic Resonance, Specialty	II	PWH	5	0	0	0	0	5

TABLE 4.2—REVIEW DEVICES IN TABLE 4.1 BY MAUDE REPORT—Continued

Device descriptions	Device class	Product code	MAUDE Reports					
			Malfunction	Death	Injury	Other	NA	Total
Solid State Fluoroscopic X-Ray Imager	II	LKG	16	1	4	0	0	21
Oxygenator, Long Term Support Greater Than 6 Hours.	II	FXY	19	0	2	0	0	21
Transmitters And Receivers, Electrocardiograph, Telephone.	II	ONT	0	0	1	0	0	1
Extracorporeal System For Long-Term Respiratory/ Cardiopulmonary Failure.	II	OMC	1	0	0	0	0	1
Catheter, Percutaneous, Intraspinal, Short Term	II	HFM	10	1	3	0	0	14
Implanted Subcutaneous Securement Catheter	II	MOS	13	0	52	7	1	73
Subcutaneous Implanted Apheresis Port	II	QHY	1	0	0	0	0	1
		Total	383	24	203	11	9	630

III. Exemption from 510(k) Premarket Notification Requirement

A. Class I Devices

Section 510(*l*)(2)(A)–(B) of the FD&C Act, 21 U.S.C. 360(*l*)(2)(A)–(B), provides that ''the Secretary shall identify through publication in the **Federal Register**, any type of class I device that the Secretary determines no longer requires a report under subsection (k) to provide reasonable assurance of safety and effectiveness'' and that ''[u]pon such publication—each type of class I device so identified shall be exempt from the requirement for a report under subsection (k); and the classification regulation applicable to each such type of device shall be deemed amended to incorporate such exemption.''

In view of the complete lack of or de minimis number of adverse events in MAUDE following FDA's waiver of the premarket notification requirement for the class I devices listed in Tables 2, 3.1, and 4.1, the Department has concluded that the premarket notification requirement is no longer required to provide reasonable assurance of the safety and efficacy of those devices. As such, as of this Notice, the 7 class I devices listed in Table 5 below shall be exempt from the 510(k) premarket notification requirement.

TABLE 5—CLASS I DEVICES IMMEDIATELY EXEMPT FROM 510(k) NOTIFICATION REQUIREMENT

Device description	Device class	Product code	Section in 21 CFR
Powder-Free Polychloroprene Patient Examination Glove	I	OPC	880.6250
Patient Examination Glove, Specialty	I	LZC	880.6250
Radiation Attenuating Medical Glove	I	OPH	880.6250
Powder-Free Non-Natural Rubber Latex Surgeon''s Gloves	I	OPA	878.4460
Powder-Free Guayle Rubber Examination Glove	I	OIG	880.6250
Latex Patient Examination Glove	I	LYY	880.6250
Vinyl Patient Examination Glove	I	LYZ	880.6250

B. Class II Devices

Section 510(m)(2) of the FD&C Act, 21 U.S.C. 360(m)(2), provides that, after a 60-calendar-day-notice comment period, ''the Secretary may exempt a class II device from the requirement to submit a report under subsection (k) . . . if the Secretary determines that such report is not necessary to assure the safety and effectiveness of the device.'' Within 120 days of publication, ''the Secretary shall publish an order in the **Federal Register** that sets forth the final determination of the Secretary regarding the exemption of the device that was the subject of the notice.'' Given the lack of any adverse event reports in MAUDE for class II and the unclassified medical devices listed in Table 2, and the lack of non-death-related adverse event reports for class II devices in Tables 3.3 and 4.2, the Department has determined that 510(k) premarket notification for the 84 class II devices and the unclassified device listed in Table 6 below is no longer necessary to assure the safety and effectiveness of those devices.

TABLE 6—CLASS II DEVICES AND UNCLASSIFIED DEVICES PROPOSED EXEMPT FROM 510(k) REQUIREMENT

Device description	Device class	Product code	Section in 21 CFR
Ventilator, Continuous, Minimal Ventilatory Support, Home Use	II	NQY	868.5895
Airway Monitoring System	II	OQU	868.5730
Impedance Measuring Device Utilizing Oscillation Techniques	II	PNV	868.1840
Gauge, Pressure, Coronary, Cardiopulmonary Bypass	II	DXS	870.4310
Valve, Pressure Relief, Cardiopulmonary Bypass	II	MNJ	870.4400
Oximeter, Tissue Saturation, Reprocessed	II	NMD	870.2700
Multivariate Vital Signs Index	II	PLB	870.2300
Electrocardiograph Software For Over-The-Counter Use	II	QDA	870.2345
Sterilizer, Dry Heat	II	KMH	880.6870
Check Valve, Retrograde Flow (In-Line)	II	MJF	880.5440

TABLE 6—CLASS II DEVICES AND UNCLASSIFIED DEVICES PROPOSED EXEMPT FROM 510(k) REQUIREMENT—Continued

Device description	Device class	Product code	Section in 21 CFR
Intravascular Administration Set, Automated Air Removal System	II	OKL	880.5445
Neuraxial Administration Set—Intrathecal Delivery	II	PYR	880.5440
High Level Disinfection Reprocessing Instrument For Ultrasonic Transducers, Liquid	II	PSW	892.1570
Pediatric/Child Facemask	II	OXZ	878.4040
Normalizing Quantitative Electroencephalograph Software	II	OLU	882.1400
Computerized Cognitive Assessment Aid	II	PKQ	882.1470
Physiological Signal Based Seizure Monitoring System	II	POS	882.1580
Computerized Behavioral Therapy Device For Psychiatric Disorders	II	PWE	882.5801
Monitor, Phonocardiographic, Fetal	II	HFP	884.2640
Monitor, Cardiac, Fetal	II	KXN	884.2600
Digital Pathology Display	II	PZZ	864.3700
Digital Pathology Image Viewing And Management Software	II	QKQ	864.3700
System, Imaging, Holography, Acoustic	II	NCS	892.1550
Lung Computed Tomography System, Computer-Aided Detection	II	OEB	892.2050
Chest X-Ray Computer Aided Detection	II	OMJ	892.2050
Computer-Assisted Diagnostic Software For Lesions Suspicious For Cancer	II	POK	892.2060
Radiological Computer-Assisted Triage And Notification Software	II	QAS	892.2080
Radiological Computer Assisted Detection/Diagnosis Software For Fracture	II	QBS	892.2090
Radiological Computer Assisted Detection/Diagnosis Software For Lesions Suspicious For Cancer	II	QDQ	892.2090
Radiological Computer-Assisted Prioritization Software For Lesions	II	QFM	892.2080
X-Ray Angiographic Imaging Based Coronary Vascular Simulation Software Device	II	QHA	892.1600
Automated Radiological Image Processing Software	II	QIH	892.2050
Image Acquisition And/Or Optimization Guided By Artificial Intelligence	II	QJU	892.2100
Apparatus, Vestibular Analysis	Unclassified.	LXV	N/A
Meter, Peak Flow, Spirometry	II	BZH	868.1860
Oximeter, Reprocessed	II	NLF	870.2700
Stethoscope, Electronic	II	DQD	870.1875
Defoamer, Cardiopulmonary Bypass	II	DTP	870.4230
Filter, Blood, Cardiotomy Suction Line, Cardiopulmonary Bypass	II	JOD	870.4270
Detector, Bubble, Cardiopulmonary Bypass	II	KRL	870.4205
Cpb Check Valve, Retrograde Flow, In-Line	II	MJJ	870.4400
Sterilizer, Ethylene-Oxide Gas	II	FLF	880.6860
Cabinet, Ethylene-Oxide Gas Aerator	II	FLI	880.6100
Purifier, Air, Ultraviolet, Medical	II	FRA	880.6500
Cleaner, Air, Medical Recirculating	II	FRF	880.5045
Controller, Infusion, Intravascular, Electronic	II	LDR	880.5725
Cleaners, Medical Devices	II	MDZ	880.6992
Percutaneous, Implanted, Long-Term Intravascular Catheter Accessory For Catheter Position	II	OMF	880.5970
N95 Respirator With Antimicrobial/Antiviral Agent For Use By The General Public In Public Health Medical Emergencies.	II	ORW	880.6260
Two Or More Sterilant Sterilizer	II	PJJ	880.6860
High Level Disinfection Reprocessing Instrument For Ultrasonic Transducers, Mist	II	OUJ	892.1570
Surgical Mask With Antimicrobial/Antiviral Agent	II	OUK	878.4040
Cerebral Oximeter	II	QEM	870.2700
Device, Sleep Assessment	II	LEL	882.5050
Standard Polysomnograph With Electroencephalograph	II	OLV	882.1400
Source Localization Software For Electroencephalograph Or Magnetoencephalograph	II	OLX	882.1400
Automatic Event Detection Software For Polysomnograph With Electroencephalograph	II	OLZ	882.1400
Amplitude-Integrated Electroencephalograph	II	OMA	882.1400
Automatic Event Detection Software For Full-Montage Electroencephalograph	II	OMB	882.1400
Burst Suppression Detection Software For Electroencephalograph	II	ORT	882.1400
Transducer, Ultrasonic, Obstetric	II	HGL	884.2960
Tonometer, Ac-Powered	II	HKX	886.1930
Tonometer, Manual	II	HKY	886.1930
Automated Digital Image Manual Interpretation Microscope	II	OEO	864.1860
Analyzer, Medical Image	II	MYN	892.2070
C-Arm Fluoroscopic X-Ray System	II	RCC	892.1650
Cannula, Arterial, Cardiopulmonary Bypass (Cpb), Embolism Protection	II	NCP	870.4210
Respirator, N95, For Use By The General Public In Public Health Medical Emergencies	II	NZJ	880.6260
Sterilizer Automated Loading System	II	PEC	880.6880
Infusion Safety Management Software	II	PHC	880.5725
Gown, Isolation, Surgical	II	FYC	878.4040
Whole Slide Imaging System	II	PSY	864.3700
Oxygenator, Long Term Support Greater Than 6 Hours	II	BZG	868.1840
Subcutaneous Implanted Apheresis Port	II	QAV	868.5454
Non-Coring (Huber) Needle	II	BYS	870.4100
Hood, Surgical	II	MAJ	868.5120
N95 Respirator With Antimicrobial/Antiviral Agent	II	OKC	880.5970
Monitor, Uterine Contraction, External (For Use In Clinic)	II	PTI	880.5570
Coil, Magnetic Resonance, Specialty	II	PWH	880.5440

TABLE 6—CLASS II DEVICES AND UNCLASSIFIED DEVICES PROPOSED EXEMPT FROM 510(k) REQUIREMENT—Continued

Device description	Device class	Product code	Section in 21 CFR
Oxygenator, Long Term Support Greater Than 6 Hours	II	FXY	878.4040
Transmitters And Receivers, Electrocardiograph, Telephone	II	ONT	878.4040
Extracorporeal System For Long-Term Respiratory/Cardiopulmonary Failure	II	OMC	882.1400
Implanted Subcutaneous Securement Catheter	II	MOS	892.1000
Subcutaneous Implanted Apheresis Port	II	QHY	892.1650

C. Impact of Exemptions on Patient Access to Medical Devices

With this Notice, the Department is immediately exempting 7 devices from the premarket notification requirement, and proposes to exempt an additional 84 devices from the requirement after public comment is closed. As noted above in Part I.A, estimates on the cost of preparing a 510(k) submission range from $100,000 to $4 million. The exemptions provided for and proposed under this Notice for these 91 device classes could eliminate anywhere from $9.1 to $364 million in startup costs if there were one new entrant into each device market. Savings could further accrue based on each new market entrant. Instead of being costs passed along to patients and taxpayers, these savings could be invested in other areas such as research and development and manufacturing.

At the same time, should these waivers go into effect as proposed, patients stand to gain more immediate access to new products that would otherwise be required to obtain a 510(k) clearance prior to marketing.

The exemptions provided for in this Notice also conserve FDA's scarce review resources. The COVID–19 PHE stretched FDA's review capacity. Under this Notice, FDA's review resources can be redeployed to review other innovative technology, to include devices designed to mitigate the impact of COVID–19.

IV. Request for Information, Data, and Further Study

HHS' review in this Notice warrants expansion and further study. FDA's medical device Product Code database contains 6,651 unique codes (to include those discussed in this Notice). Of those unique codes, 157 are for class I devices that require 510(k) clearance, and 2,662 are for class II devices that require 510(k) clearance. Applying the $100,000 to $4 million in estimated costs for 510(k) preparation and submission to these 2,819 devices yields approximately $281.9 million to $11.276 billion in startup costs, assuming one new market entrant in each of the 2,819 device classes. Further, again assuming a 90-day review period and one new device entrant in each of the 2,819 device classes that require 510(k) notification, FDA's current approach creates 253,710 review days or 695.1 review years between Americans and new devices. The question of whether the 510(k) notice is justified in view of safety and efficacy concerns merits comprehensive analysis for the benefit of Americans. The Department seeks public comment, research, and analysis on whether other devices should be exempt from the premarket notification requirement.

At a more detailed level, the Department observed internal inconsistencies in FDA's regulation of some device classes that merit discussion. Manual stethoscopes are exempt from the premarket notification requirement. 21 CFR 870.1875(a)(2). Electronic stethoscopes are also exempt, but only if the device ''is a lung sound monitor.'' 21 CFR 870.1875(b)(2). Similarly, FDA exempts ''clinical mercury thermometer . . . device[s] used to measure oral, rectal, or axillary (armpit) body temperature using the thermal expansion of mercury'' from the 510(k) premarket notification requirement. 21 CFR 880.2920. By contrast, clinical electronic thermometers which never enter into any body orifice require 510(k) premarket notification. 21 CFR 880.2910. These apparent inconsistencies merit scientific scrutiny. To that end, the Department seeks public comment as to whether other inconsistencies in the medical device regulatory framework exist.

Dated: January 8, 2021.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

[FR Doc. 2021–00787 Filed 1–14–21; 8:45 am]

BILLING CODE 4150–26–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1657]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Survey of Drug Product Manufacturing, Processing, and Packing Facilities

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by February 16, 2021.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comment'' or by using the search function. The title of this information collection is ''Survey of Drug Product Manufacturing, Processing, and Packing Facilities.'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.